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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Via Federal Express

Re: Docket No. 98N-1265

Dear Sir/Madam:

These comments are in response to the request for comments concerning the Food and Drug Administration's ("FDA") Federal/State Memorandum of Understanding on the Interstate Distribution of Compounded Drug Products ("MOU") published in the Federal Register on March 23, 1999. We oppose the Draft MOU. These comments represent the opinions of the law firm of Brown & Fortunato, P.C. and do not necessarily reflect the views of our clients.

I. Background

Historically, the FDA and the state boards of pharmacy have been at odds over how to regulate compounded pharmaceutical products. The FDA has taken the view that because compounded drugs were not FDA-approved drugs they were adulterated and misbranded, and therefore, subject to FDA jurisdiction and sanctions. In contrast, the state boards of pharmacy and the pharmacy community recognized that compounded drugs are an integral part of the practice of pharmacy, serving important patient needs. Accordingly, the state boards of pharmacy took the view that drug compounding fell under their respective jurisdictions.

Because of the continued discord between the FDA and the state boards of pharmacy, and because of concerns expressed by large pharmaceutical manufacturers, Congress included in the Food and Drug Administration Modernization Act of 1997 ("Act") a statutory provision dealing with the interstate distribution of compounded drug products. The Act recognizes that issues related to drug compounding should be left to regulation by the states under ordinary circumstances. It also acknowledges that there are circumstances where joint state and federal action is required, such as the interstate distribution of compounded drugs. See letter of Senator Ben Nighthorse Campbell to Acting FDA Commissioner Friedman, dated September 9, 1998 ("Collaboration between the FDA and state regulatory authorities in developing the regulations required by the new statute will support those state authorities in their oversight of compounding activity").

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To define the roles of the state boards of pharmacy and the FDA regarding the interstate distribution of compounded drug products, the Act essentially directed the states and the FDA to enter into a memorandum of understanding on the interstate distribution of compounded drug products. Many states were concerned about the Act's impact on compounding pharmacies, and, as a result, quickly drafted memoranda of understanding concerning the interstate distribution of compounded drugs.

All of the state memoranda of understanding that have been submitted to the FDA and included on the FDA's website allow for interstate distribution of compounded drug products in an amount greater than 20% of a pharmacy's total prescription orders, provided certain procedures are followed.[1] Not one of the state-proposed memoranda of understanding seeks to put an artificial limit on the amount of compounded drug products that may be shipped interstate. Instead, the state-proposed memoranda of understanding establish a sensible regulatory framework that requires pharmacies desiring to ship compounded drug products interstate to inform the state board of pharmacy before beginning shipment and to subject themselves to oversight by the applicable state board of pharmacy.

II. Analysis

A. The Draft MOU is inconsistent with Congressional intent

The purpose of the compounding provisions of the Act is to ensure "continued availability of compounded drug products as a component of individualized therapy, while limiting the scope of compounding so as to prevent small-scale manufacturing under the guise of compounding." S.

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[1] Colorado: "A prescription drug outlet may dispense prescription orders for compounded drugs to be shipped interstate in an amount greater than 5% of its total prescription orders dispensed during the same calendar year. The PDO shall comply with all applicable state and federal laws, rules and regulations, including out of state registration/licensure and other applicable requirements which may be imposed."

New Hampshire: "A pharmacy may dispense compounded drugs interstate in an amount greater than 5% of its total drugs dispensed or distributed, provided that the pharmacy notifies the state board of pharmacy with which it is licensed or registered and provides additional information that may be required by that state board of pharmacy."

South Carolina: "A pharmacy may dispense compounded drugs interstate in any amount greater than 5% of its total drugs dispensed or distributed, provided that the pharmacy notifies the state board of pharmacy with which it is registered and provides additional information that may be required by the state board of pharmacy."

Rep. 43, 105th Cong., 1st Sess. 68 (1997). The Act's clear intent in addressing compounding was to ensure that compounded drug products remained available to the public. See http://www.iacprx.org.legistlativ_update.htm (setting out a letter in which forty-three members of Congress state that by passing the Act, Congress wished to ensure that patients would have access to compounded medications prescribed by their physicians.); see also comments of Ms. Kate Lambrew Hull, Legislative Assistant to Senator Tim Hutchison, at the October 14, 1998, meeting of the Committee on Pharmacy Compounding ("It was Congress' intent, in drafting Section 127, to provide a safe harbor for legitimate pharmacy compounding activities"). Moreover, as Ms. Hull noted in her comments to the Pharmacy Compounding Committee, it is also clear that Congress did not intend that the "MOU provision set a floor or a ceiling with regard to the quantity of [compounded drug] product that enters into interstate commerce." Hull Comments.

B. The FDA Exceeded its Authority in the Draft MOU

In imposing the twenty-percent ceiling on the interstate shipment of compounded medications, the FDA has exceeded its authority under the Act. The Act provides only that "[t]he Secretary shall, in consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by the States in complying with subparagraph (B)(i) [concerning a state entering into a memorandum of understanding]." Nothing in the Act or the legislative history supports the FDA's unilateral decision to impose an arbitrary percentage limitation on the amount of compounded medications that may be shipped interstate. Indeed, the FDA cannot, and did not, cite any statutory or regulatory authority supporting its unilateral decision to create an arbitrary twenty-percent ceiling.

Moreover, if Congress had intended to limit the interstate shipment of compounded medications it would have done so itself or specifically directed the FDA to do so. It did not. And the FDA cannot now use Congress' inaction on this issue as a basis to impose an ill-conceived limitation on the interstate distribution of compounded drug products.

C. Public Policy Considerations.

Pharmacists fill millions of compounded prescriptions per year for all types of patients. Some patients simply need a dye or other allergen removed from a medication, others need a medication in a form or strength not commercially available, and others require new formulations suited to their individual needs. Specialized compounding pharmacies are able to provide all of these services.

1. The Twenty Percent Limitation Punishes Specialized Compounding Pharmacies.

Just as with other industries, the pharmacy industry is increasingly specialized. And, as a result, certain pharmacies have specialized in compounding only a limited class of drugs. See Introductory Comments of Dr. Randy P. Juhl at the October 14, 1998, Meeting of the Pharmacy Compounding Advisory Committee (hereinafter "Juhl Comments"). For example, some pharmacies specialize in natural hormone replacement drugs, and others specialize in noncommercially available animal drugs. The reason these pharmacies have been able to specialize is twofold. First, there is a market need for these types of drugs, and, second, these specialized compounding pharmacies have found a method to provide the services better than other pharmacies. Furthermore, many local pharmacies cannot or will not compound custom medications because of the expense and skill level required. Because of their expertise, many of these specialized pharmacies have developed a national reputation and now receive prescription orders nationwide.

However, this type of specialization does not come without a price. These compounding pharmacies have had to invest in new specialized equipment and in hiring and training qualified individuals in order to meet the needs of their customers. Moreover, many of these pharmacies have had to abandon or significantly curtail other aspects of their pharmacy practice in order to devote their resources to dispensing compounded prescriptions. Consequently, many compounding pharmacies derive all or a significant portion of their revenues from the sale of compounded drugs. If these specialized pharmacies were limited to shipping only 20% of their prescriptions interstate, they would be put out of business. They simply would have insufficient revenues from local sales to support their operations.

2. The Twenty Percent Limitation Punishes the Public.

The public benefits from the existence of specialized compounding pharmacies. There are three significant benefits derived from specialized compounding pharmacies that would be eliminated by the twenty-percent limitation.

(a). The MOU would decrease the accessibility to necessary compounded drugs.

Patients that need compounded drugs currently have access to a number of different pharmacies throughout the country that can service their needs for compounded medications. If a patient does not have confidence in, or is unhappy with, the local pharmacy, or the local pharmacy cannot or will not compound, the patient can contact a mail order pharmacy to get a compounded prescription, and the prescription order can be delivered right to his or her door. This is particularly advantageous for elderly or disabled persons who have difficulty getting out of their homes.

Under the draft MOU, patients will be unable to have their prescription orders for compounded medications dispensed by a mail order pharmacy. But the need for compounded medications will not go away. As a result, patients will be forced to rely on the corner drugstore, which may have little or no experience in compounding, to fill their compounded prescription needs. Having an inexperienced pharmacy dispense compounded medications increases the risk that a patient may be harmed by an improperly compounded medication.

And what if the corner drugstore cannot or will not fill a prescription order for a compounded medication? Presumably, the elderly and disabled patients will have to drive themselves to the nearest pharmacy willing or able to fill their prescription, or go to the expense of having someone pick up their medication for them. In many areas, this poses a tremendous problem for the elderly.

(b). The MOU will make compounded drugs more expensive.

One of the advantages of specialized compounding pharmacies is that, due to economies of scale, the pharmacy can purchase the necessary compounding ingredients at a cheaper price and then pass the savings to the patient. Furthermore, because these pharmacies have the necessary equipment and expertise, they produce the compounded drug products more efficiently than ordinary retail pharmacies.

The draft MOU, because it effectively eliminates specialized compounding pharmacies, will drive up the cost of compounded drug products. The local pharmacist who will now be forced to fill prescription orders for compounded medications will have to purchase expensive new equipment, will not be able to purchase bulk quantities of the drug, and will not have the necessary skill or experience to make these products as efficiently as the specialized compounding pharmacy. In order to offset these increased costs, the local pharmacist will have to charge patients significantly more than they were being charged for the same product by the specialized compounding pharmacy.

(c). The MOU will make compounded drugs less safe

The elimination of specialized compounding pharmacies will result in more dangerous compounded drug products. Yet, such a result is exactly what the Act was designed to prevent. To be proficient at compounding, a pharmacist must have the educational background and sufficient training and experience. See Juhl Comments ("However, there has also been a downside to pharmacy compounding. There are those who perhaps lack sufficient training, skills, and equipment to conduct compounding."). Although many pharmacy programs now include compounding in their curricula, there was a period when compounding was not taught in pharmacy programs. Many of the pharmacists that graduated from programs that did not teach compounding are practicing today. Furthermore, many pharmacists have never compounded medications in practice and are unfamiliar with the techniques of compounding. Compounding is not an activity that can be done on an infrequent basis without the erosion of skills.

The local pharmacist who engages in a limited amount of compounding is also not subject to the self-regulating aspects of the market that currently exists for specialized compounding pharmacies. In addition to having greater experience and training than the local pharmacist, specialized compounding pharmacists have an economic incentive that ensures that their compounded products are safe for patients. Specialized compounding pharmacies must rely on their reputations for providing safe, effective drug products to generate new prescription orders. Therefore, if a specialized compounding pharmacy does not compound a drug product properly, it will develop a reputation as producing an unsafe product. Such a reputation could eventually cause the compounding pharmacy to lose all or a significant portion of its business. Eventually, the specialized compounding pharmacy will be forced to close. On the other hand, if a local pharmacist does not compound a drug product properly, he stands to lose only the business of that particular patient, and perhaps, the prescribing doctor, which is not a significant drain on his revenue. Thus, the local pharmacist does not have the same incentive as the specialized pharmacist has to ensure that his compounded drug products are safe.

D. The Twenty-Percent Ceiling is Unsupportable

The twenty-percent ceiling on interstate shipments is an example of arbitrary regulation. There is no study or even anecdotal evidence to support the proposition that the interstate shipments of compounded medications in an amount greater than twenty-percent of a pharmacy's prescriptions constitute commercial manufacturing under the guise of compounding.[2] Members of our law firm have telephoned various individuals at the FDA to determine the rationale for the twenty-percent figure, but no one was able to provide a justification for this figure. In fact, it literally appears to have been picked out of the air. One individual indicated that the twenty-percent was arrived during informal discussions. Drafting regulations that contain specific numerical guidelines to implement an act of Congress should not be undertaken so lightly or with so little justification.

Furthermore, the FDA has not defined "commercial manufacturing under the guise of compounding." The regulatory guidance has focused only on qualitative, rather than quantitative, factors. For example, commercial manufacturing is said to occur in the absence of a valid patient-physician-pharmacist relationship, regardless of whether the pharmacy compounds one or one thousand prescriptions. Likewise, if a very large pharmacy is compounding one type of medication and shipping it interstate, such amounts might be amounts typically associated with commercial manufacturing. However, if that same pharmacy is compounding and shipping a number of different products, then the amount of each individual product might not be enough to be consistent with amounts typically associated with commercial manufacturing. Similarly, a small pharmacy certainly will have an insufficient volume of compounded drug product, even if the majority of its business is devoted to compounding, to be consistent with ordinary commercial drug manufacturing. Nevertheless, under the draft MOU, both pharmacies would be in violation of the draft MOU.

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[2]Similarly, there is no support for the five percent limitation on the interstate shipment of a single compounded product or the fifty-mile limitation on the definition of local, especially in rural areas.

III. Conclusion

The FDA and large pharmaceutical manufacturers are properly concerned about commercial manufacturing under the guise of compounding; however, the current draft MOU is not the proper means of addressing this concern. The current draft MOU with its twenty-percent limit on interstate distribution of compounded medications is arbitrary and not supported by the Act. Furthermore, it hurts specialized compounding pharmacies and the public, without providing a corollary benefit. The proposed state MOUs set out a variety of logical and reasonable solutions to the problem of manufacturing under the guise of compounding. We strongly urge the FDA to abandon the current draft MOU and create a new MOU consistent with the MOUs submitted by the states. In particular, the new MOU should eliminate the arbitrary twenty-percent ceiling on interstate shipment of compounded medications.

Sincerely,

BROWN & FORTUNATO, P.C.

Jeffrey S. Baird

Heidi Kocher

JSB/jm

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